Protocol Writing Guidelines

A well-written research protocol should be detailed enough that that it contains all of the necessary information to make sound judgment on potential benefits versus risks to human research subjects. It should read easily and not contain extensive, complex or esoteric information. The protocol should give the reader a clear picture of what the benefits of the research are, how the experiment will be conducted and what the risks, exposures and discomforts to humans subjects are.

The following guide is designed to be used with the protocol template. Please pay close attention to the descriptive items in blue for each section. In addition to these guidelines, the following are general notes concerning areas where mistakes are usually made:

- Spelling and grammar – use the spell checker and proofread the document
- Format – please follow the template format exactly
- Acronyms – spell out the first time it is used, even the most well known acronyms
- Protocol MUST be a standalone document. Assume that the reader knows nothing about your specific operation/facility.
- Ensure that the protocol and ICD match with respect to experimental procedures, time commitment, etc.

Title of Investigation - Be succinct and specific.
F-WR-2005-0027-H

1. **Principal Investigator**
   Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address
   Identify contractor affiliation if applicable
   Person with authority to make decisions and give authoritative answers to questions.

2. **Associate Investigators**
   a. Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable, brief description of role in the study
   b. Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable, brief description of role in the study
   c. Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable, brief description of role in the study
   All other persons who will interact with subjects or with protected data.

3. **Medical Consultant or Monitor**
   Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address
   Disinterested physician (generally) who is familiar with the protocol and its demands on subjects. The medical consultant or monitor can also be another medical professional as required by the nature of the study. Often it is the flight surgeon where work will be

carried out. See AFI 40-402 and AFRLI 40-402 regarding specific guidance on medical consultants, monitors and observers.

4. **Facility/Contractor**

Start here…do not indent paragraphs…space between each paragraph
Identify all locations and/or unique facility settings that will be employed during the research activity. If this is a collaborative/multi-center study, identify the other participating facilities/institutions.

List all contractors and sub-contractors (name of agency, name of **program manager** and contact info and **contract number**) involved and the nature of support provided:

- Personnel – do they interact with human subjects?
- Equipment
- Facility
- Funding

If the contractor is engaged in Human Subjects Research (e.g. interacts or intervenes with a human subject for the purposes of research) an Assurance of Compliance will be required. If the contractor has an Assurance, either with OHRP or DoD, please list the Assurance number. If the contractor does not have an Assurance the contractor may be required to obtain one.

5. **Conflicts**

State "None" or provide description of conflict**.** Include any financial interests, duty position conflicts (e.g., Investigator and Program Manager in same study), along with plan to manage such conflict in this study.

6. **Objective**

Start here…do not indent paragraphs…space between each paragraph
Why are you doing this? Brief paragraph.

7. **Background**

Start here…do not indent paragraphs…space between each paragraph
Keep this brief and write in plain English.
Hypothesis or question to be answered and scientific rationale. Include sufficient (not exhaustive) relevant cited literature offering the IRB an understanding of the context (how this activity fits into the field of similar work) and the rationale (how this activity adds to existing knowledge).

8. **Impact to Air Force Mission**

Start here…do not indent paragraphs…space between each paragraph
How will completion of this project contribute to the Air Force or DoD mission? Why is it important to us?

9. **Experimental Plan**

a. Equipment:

Start here…do not indent paragraphs…space between each paragraph
Briefly describe equipment that will be used in the study especially as it relates to human subject use. For example, devices that the subject will wear or directly interact with are important. There is no need for detailed description of video or computer equipment.

b. Subjects:

Start here…do not indent paragraphs…space between each paragraph
The following items **MUST be included** in this section:

- total number of subjects that you will recruit. Keep in mind that once a subject signs an ICD, that person will count against this number. If you intend to study 20 subjects, you should ask for 25 -30 perhaps based upon historical attrition rates for your experiments (may vary based upon nature of experiment, duration, etc.) Do not exceed this number. If you need more subjects, please submit an amendment request.
- inclusion/exclusion criteria
- population where subjects will be selected from (active duty, reserve, DoD civilians, non-DoD civilians, students, patients, company employees)
- male/female ratio of subjects
- age range of subjects
- whether any special subjects (45 CFR 46 subparts B-D) will be involved
- compensation (if any) that will be offered to subjects. If there is no compensation, please state so.
- qualifications and time commitment for each subject (be very specific)
- screening for subjects and special tests required. The subject must sign an ICD before any screening takes place.
- recruitment procedures and materials – see FAQ on web site for guidance on recruiting – be very detailed
    - if any posters, fliers or emails will be used the IRB must see a copy!
    - minimize the possibility of coercion or undue influence
    - who will recruit subjects and how
    - You can state that subjects will be compensated, but the recruiting material should not have dollar amounts.

c. Duration:

Start here…do not indent paragraphs…space between each paragraph
How long—under normal circumstances—do you expect data collection to take.

d. Description of experiment, data collection, and analysis:

Start here…do not indent paragraphs…space between each paragraph
Please include pertinent information here that describes clearly the design of the experiment, **how data will be collected** and **analyzed** and **what a subject will**

experience as a participant in the investigation. Summarize all pertinent information needed to offer IRB members the ability to follow the complete course of the experimental session, and perform an adequate evaluation of the experimental design and equipment to be used. Essential information to be included in this section are the experimental design, methodology and instrumentation, data collection, security of the collected data (e.g., personal information) and the proposed analysis of the data collected. Also, please use language in this section that can be understood by a wide range of technical personnel. Not all IRB members are experts in your specific field of study.

If this protocol builds upon another protocol, provide reference to that protocol here. In addition to referencing the previous study, provide a brief description of the study. For example, if there is a general protocol used to select and train subjects for a permanent subject test panel it must be referenced.

e. Safety monitoring:

Start here…do not indent paragraphs…space between each paragraph
Safety monitoring is usually only applicable to high-risk studies. If study is high risk or requires a medical monitor include who will monitor, if a medical observer will be on-site or immediately available and how they are contacted in the event of an emergency. Include information on any **special Safety Precautions** that are in place.

f. Confidentiality protection:

Please outline your **storage and security procedures** to guard against unauthorized access of personal information. Include how long you propose to keep personal information. Personal information should not be kept longer than is required for the purposes for which the information may lawfully be used. As a general principle, data that contains personal identifiable information should be kept in appropriate secure storage within the research facility (in a locked cabinet in an office that is locked when not occupied). Electronic files with personal information should be password protected and stored on a secure server. Neither hard copy or electronic files containing personal information should be removed from the facility or stored in a non-secure manner electronically (disk, thumb drive, laptop, personal computer).

9. Risk Analysis

Start here…do not indent paragraphs…space between each paragraph
Describe **all possible hazards, risks and discomforts** to include both physical and psychological risks. For each identifiable risk, the IRB needs information on its incidence, the availability and effectiveness of treatment, and possible long-term or permanent effects. Also include information on efforts taken to minimize these risks and maximize safety.

10. References

a. Reference

b. Reference
c. Reference

11. Attachments

a. Informed Consent Document
b. Curriculum vitae of investigators
c. Questionnaires or surveys (if applicable)
   Include medical screening questionnaires
d. Subject recruiting materials (if applicable)
   Include emails, letters, newspaper ads, briefings, posters or any other material that will be used for purposes of recruiting subjects
e. Other attachments if applicable, such as: letters of collaborative support, IND/IDE supportive documents, contractor assurances, and any other supportive documentation.